K032051

JAN - 9 2004

ACCESS Battery, Inc.

Power When It Matters Most! ™

510(k) Summary

Rechargeable Battery Packs

Submitter: Access Battery, Inc.
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Date Prepared: October 31, 2003

Device Name:

Trade/Proprietary Name:	Battery, Rechargeable
Common/Generic Name:	Battery, Rechargeable
Classification Name:	Box, Battery, Rechargeable Batteries, Rechargeable

Classification:	**Cardiovascular Panel**	**Class**
21 CFR 870.1025	Detector and Alarm, Arrhythmia	III
21 CFR 870.1130	System, Measurement, Blood Pressure, Non-Invasive	II
21 CFR 870.2300	Monitor, Cardiac (Including Cardiotachometer & Rate Alarm)	II
21 CFR 870.2340	Electrocardiograph	II
21 CFR 870.5300	DC Defibrillator, Low Energy (Including Paddles)	III

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510(k) Summary

Legally Marketed Predicate Devices:

This submission compares the specifications and functionality of various rechargeable battery packs with those of similar devices that were included as part of the following original predicate equipment and submissions:

1. The Access Battery MLA0051 is the same as that used in CAS Medical Systems Series 9000 Blood Pressure Monitors, cleared under 510(k) Notifications K982135 and K925402.
2. The Access Battery MLA90479 is the same as that used in Spacelabs Medical Models 90478 and 90479 Telemetry Receivers, cleared under 510(k) Notification K925510.
3. The Access Battery MNC1000EKG is the same as used in the Marquette Model 1200 Defibrillator, cleared under 510(k) Notification K882067.
4. The Access Battery MNC1659L is the same as that used in the PPG Biomedical/Litton EK Series EKG Monitors, cleared under 510(k) Notifications K890875 and K832015.
5. The Access Battery MNC4755 is the same as that used in Hewlett Packard's 4700 Series EKG Pagewriter Electrocardiograph, cleared under 510(k) Notification K802718.
6. The Access Battery MNC14649P is the same as that used in the Datascope/Medical Research Laboratories Passport Monitor & Defibrillator DPD, cleared under 510(k) Notifications K952085 and K930548.
7. The Access Battery MNC862988P is the same as that used in Burdick Eclipse 4 Model Electrocardiograph, cleared under 510(k) Notifications K946281 and K943959.
8. The Access Battery MNC431345P is the same as that used in Siemens Medical Bedside Monitoring System SC9000, cleared under 510(k) Notifications K970920 and K962291.

Description:

Rechargeable batteries and battery packs are utilized as a primary direct current (d-c) power source or as a standby or backup d-c power source for portable as well as stationary medical equipment.

Statement of Intended Use:

To power the functions of various devices for which the batteries or battery packs are configured.

Comparison of Technological Characteristics

The design components and functionality of the various battery packs listed are similar to those of their predicate devices. All these devices provide a means of supplying electrical power through chemical reaction. The energy provided depends upon the voltage and capacity rating of a particular pack and the amount of current used by the device into which they are installed. The performance and life span of a rechargeable battery depends on operating conditions of temperature, current drain, and the charge/discharge method. These parameters are taken into account in designing such batteries. The goal is to develop battery packs that maintain capacity for as high and as long as possible. Typical cell chemistries are Lead Acid (SLA), Nickel-Cadmium (NiCd), and Nickel-Metal Hydride (NiMH).

Testing:

Safety and performance testing of these battery packs have been performed to ensure that these devices meet all functional requirements and performance specifications.

In comparison analysis, the predicate devices set the benchmark. The replacement devices must meet or exceed these benchmark results consistently.

Concerns that are addressed during bench test comparison analysis are:

Life cycle - The replacement device must provide as many or more recharge/discharge cycles as the predicate device.

Temperature – The replacement device must function correctly over the same temperature range as the predicate device.

Mechanical & Electrical Component Integrity

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 3 - 2008

Access Battery, Inc.
c/o Mr. Alexander B. Henderson
Technical Manager
5357 Highway 86
Elizabeth, CO 80107

Re: K032051
Trade Name: Rechargeable Battery
Regulation Number: 21 CFR 870.5310
Regulation Name: Automated External Defibrillator
Regulatory Class: Class III (three)
Product Code: MKJ
Dated: October 31, 2003
Received: November 3, 2003

Dear Mr. Henderson:

This letter corrects our substantially equivalent letter of January 9, 2004. We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ACCESS Battery, Inc.

Power When It Matters Most! ™

INDICATIONS FOR USE STATEMENT

510(K) Number. K032051

Device Name: Box, Battery, Rechargeable

Indications for Use:

To power the functions of various devices for which batteries or battery packs are configured.

Since rechargeable batteries and battery packs are "device specific" and are designed to operate and fit into the equipment for which they were manufactured, only qualified personnel should evaluate, test, charge, or install these devices.

This battery is shipped only to customers who request a replacement battery for a particular device or to replace a competitor's replacement battery. Biomedical equipment service professionals therefore know that the intended use is as a replacement battery.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

X Prescription Use

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K032051

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